Essential Health Benefits Prescription Drug Standard

Issue No.1 – Formulary Transparency

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Introduced by the Affordable Care Act (ACA), Essential Health Benefits (EHB) are a set of ten health care service categories that plans must cover.[1] One of the ten categories of benefits is prescription drugs.

On February 20th, 2015, the Department of Health and Human Services (HHS) issued the Notice of Benefit and Payment Parameters for 2016 final rule (Final Rule 2016), which finalized changes to the EHB standard.[2] The Final Rule 2016 significantly modified the EHB prescription drug requirements.

This fact sheet, focusing on **formulary transparency**, is the first in a series of NHeLP fact sheets describing the EHB prescription drug standard. Additional fact sheets in this series examine the exceptions process, the use of the United States Pharmacopeia to establish minimum coverage standards, Pharmacy and Therapeutics (P&T) Committees, and new restrictions on mail-order only pharmacies.

Background – Drug Formulary Transparency

In 2014 and 2015, some Qualified Health Plans (QHPs) offered through ACA Marketplaces failed to provide a direct link to the plan's formulary on the Summary of Benefits and Coverage (SBC). The ACA requires plans to provide the SBC showing the plan benefits and costs to allow consumers to compare plans and make informed choices when purchasing a QHP.[3]

In April 2014, the consulting firm Avalere released a study assessing the accessibility of prescription drug formularies for QHPs sold in select State-Based Marketplaces and the Federally Facilitated Marketplace. The study found that 38% of QHPs provided no drug formulary information at all.[4] In California, consumer groups led by the American Cancer Society Action Network helped enact a law requiring all health plans offered through the state's Marketplace (Covered California) to post their formularies online using a standardized template.[5]

Consumer groups raised various concerns over the lack of prescription drug formulary transparency in comments to HHS' Notice of Benefit and Payment Parameters proposed rule for 2016, including:[6]

- Incomplete formularies:
  - Issuers listed commonly prescribed medications, but not the complete QHP prescription drug formulary;
  - Plans provided little or no information for prospective enrollees on out-of-pocket expenses such as co-pays and co-insurance for prescription drugs;
  - Plans failed to explain the tiering structure for drug formularies and failed to provide readily accessible information on prior authorization, quantity limits, or other restrictions.
- Inaccessible formularies:
  - Plans that did make formularies available often did so by providing links to the insurer's homepage and requiring multiple clicks until the consumer could access the appropriate plan formulary;
  - Plan formularies were often difficult to distinguish when issuers offered multiple products with similar-sounding names and failed to provide direct links to plan formularies.
- Changing formularies:
  - Issuers failed to update their online formularies and would drop medications from the formularies without notice.

As a result, many consumers lacked adequate information to make side-by-side comparisons of plans' prescription drug coverage at the time of plan selection. In comments to HHS' proposed rule, NHeLP and other advocates urged HHS to address these concerns by requiring issuers to:

- Publish up-to-date, complete QHP formularies with tiering and any restrictions on accessing the drug;
- Include information on cost-sharing tiers and utilization controls, such as prior authorization or step therapy requirements;
- Provide a reasonable estimate of what the actual patient cost-sharing would be for plans charging co-insurance;
- Indicate preferred and non-preferred drugs; and
- Provide information about how to obtain drugs that are not covered under the plan's prescription drug benefit.

Advocates and HHS also proposed requiring plans to make their formularies available in a "machine-readable" or other format so that outside entities can aggregate prescription drug information. For example, the Medicare Part D program enables plan finders or

benefit calculators to match an individual's prescriptions and provider needs with a range of appropriate plans.

Change/Clarification

In the Final Rule 2016, CMS adds a new section 45 C.F.R. § 156.122(d) requiring greater transparency in QHP prescription drug formularies beginning in 2016. The new rule requires health plans to publish an up-to-date, accurate and complete list of all covered drugs on its formulary drug list, including the tiering structure adopted and any restrictions on how to obtain the drug.[7] The rule requires that formulary information must be easily accessible to plan enrollees, prospective enrollees, and the general public through a clearly identifiable tab or link.[8] The Final Rule 2016 also requires plans in the Federally Facilitated Marketplace to submit formulary information to HHS in a format to be specified by HHS, but does not specify a "machine-readable" format.[9]

Advocacy Opportunities

Advocates can work now to help ensure effective implementation of new QHP formulary transparency requirements in 2016. To begin with, advocates can review the 2015 QHP formularies to identify which plans are more transparent. In reviewing current formularies, advocates can document deficiencies to push for enhanced transparency requirements in future federal rulemaking. For example, while the 2016 Final Rule improves transparency in QHP formularies, it falls short in several key areas.

- HHS decided not to require detailed information on cost-sharing, but instead encouraged issuers to provide such information "as feasible."[10]
- The Final Rule 2016 does not define an "up-to-date" formulary. However, the preamble notes that HHS expects plans to keep their online formulary lists current.[11]
- Issuers are not required to provide enrollees and potential enrollees with cost estimates for co-insurance.

Advocates should also monitor plans' contraceptive coverage to ensure that there are no cost-sharing, tiering, or utilization controls that block or delay access to a woman's preferred contraceptive method. In addition, advocates can push for more robust standards at the state level, through legislation and administrative advocacy. Finally, when the new transparency requirements take effect in January 2016, advocates should monitor compliance and urge state and federal enforcement of the formulary transparency standards.

Conclusion

Although the Final Rule 2016 did not fully address all of the concerns raised by health advocates, the changes to QHP formulary transparency resulted in significant steps forward. Beginning in 2016 (or sooner in some states), health care consumers will have new tools and information to make informed choices when selecting a health plan. Moreover, the new formulary transparency requirements demonstrate the importance of advocacy efforts and lay the groundwork for future improvements in EHB prescription drug standards.

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[1] The ten EHB statutory categories of benefits are: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services (including chronic disease management); and pediatric services, including oral and vision care. The EHB requirement applies to non-grandfathered health plans offered in the individual and small group markets (both inside and outside the Marketplace). This fact sheet focuses on EHBs as they apply to the private market.

[2] HHS Notice of Benefit and Payment Parameters for 2016 Final Rule, 80 Fed. Reg. 10,750 (Feb. 27, 2015) (to be codified at 45 C.F.R. pts 144, 147, 153, 154, 155, 156, and 158), *available at* http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf [hereinafter Final Rule 2016].

[3] 42 U.S.C. § 300gg–15.

[4] Avalere, Exchange Consumer Experience Analysis (April, 2014) *available at* http://avalerehealth.com/expertise/managed-care/insights/avalere-analysis-exchange-consumer-experience.

[5] SB 1052 (Approved by Governor Sept. 25, 2014), now codified at Cal. Health & Safety Code § 1367.205.

[6] *See e.g.*, American Cancer Society Cancer Action Network, Re: CMS-9944-P – Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters for 2016 (Dec. 22, 2014) *available at* http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0209; California Chronic Care Coalition, Comments on Notice of Benefit and Payment Parameters for 2016 (Dec. 19, 2014) *available at* http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0071; HIV Health Care Access Working Group, Comments on Notice of Payment and Benefit Parameters for 2016 Rule; Ohio Consumers for Health Coverage, Comments on Benefit and Payment Parameters for 2016 (Dec. 22, 2014) *available at* http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0257; National Health Law Program, Comments - Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016 (Dec. 22, 2014), *available at* http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0276.

[7] 45 C.F.R. § 156.122(d).

[8] *Id.* § (1)(i).

[9] *Id*. § (2).

[10] Final Rule 2016, *supra* note 2, at 10,810.

[11] *Id*. at 10,829.